

PATENT
AFEI:002US

| |
|-----------------------------------|
| CERTIFICATE OF EXPRESS MAILING |
| NUMBER EL 794535394 US |
| DATE OF DEPOSIT February 15, 2002 |

APPLICATION FOR UNITED STATES LETTERS PATENT
for
DEVICES AND METHODS FOR POSITIONING SUTURES
by
Alexander J. Feigl

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to the field of medical devices. More particularly, it relates to an instrument used in the field of suture placement during surgery. Even more particularly, it relates to an instrument that may be used to position one or more needles in locations that are difficult to suture using conventional methods.

2. Description of Related Art

In the field of medical surgery, suture placement is an integral part of the vast majority of operations. Many surgical procedures entail the placement of a difficult stitch or stitches. Traditional needle advancement and positioning instruments almost exclusively use a hemostat-like tool that allows a needle to be gripped by the tool and then advanced into the tissue being sutured. For instance, in either open or traditional laparoscopic suturing procedures, a needle is often grasped by one of these traditional instruments, and the needle, along with the suture coupled to the needle, is placed in the desired position and driven through tissue. The needle is then exchanged or adjusted with a second instrument.

Such tools are disadvantageous because it is often difficult for a doctor to grasp and position the needle. Additionally, many of these devices only allow for the placement of a single needle at a time. Furthermore, using traditional devices to position multiple needles in the tissue of a patient is also time consuming, and is therefore detrimental to the patient as the length of the surgical procedure is increased. A need therefore exists for an instrument that would allow for the precise and rapid positioning of needles during surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to a medical device for positioning sutures in the body of a surgical patient. In one embodiment, the device comprises a body, a lumen, and a first needle guide channel. A "lumen" is simply a passageway. The body of the device may have a variety of shapes that are advantageous for the placement of the

1 device within the body of the patient. In one embodiment, the body may be tapered at
2 one end.

3 The lumen is formed in the body, and extends from a first lumen opening formed
4 in the body to a second lumen opening formed in the body. The lumen is of sufficient
5 diameter to receive a length of suture.

6 The first needle guide channel is also formed in the body, and may extend from a
7 first needle guide channel opening formed in the body to a second needle guide channel
8 opening formed in the body. In another embodiment, the needle guide channel may
9 extend from only a first needle guide channel opening formed in the body. The needle
10 guide channel may have a variety of shapes. For example, in one embodiment, the needle
11 guide channel is arcuate shaped. As used herein, an "arcuate" shaped needle guide
12 channel need not be a perfect arch. Instead, such a needle guide channel is curved, and
13 may or may not have a break in the curve, provided a curved needle can still move within
14 the needle guide channel. The lumen and first needle guide channel are configured in
15 operative relation with each other such that a needle is backloaded into the first needle
16 guide channel will be advanced out of the first needle guide channel by pulling on a
17 length of suture that is connected to the needle and threaded through the lumen.

18 The medical device may also comprise a handle coupled to the body. The handle
19 may be coupled to the body by a connector piece. The connector piece may be bendable
20 such that it can be fixed in a variety of positions.

21 In another embodiment, the device may comprise a plurality of needle guide
22 channels. Each of the one or more needle guide channels may extend from its own first
23 needle guide channel opening formed in the body to its own second needle guide channel
24 opening formed in the body. In another embodiment, each of the one or more needle
25 guide channels will extend from only its own first needle guide channel opening formed
26 in the body. Each of the one or more additional needle guide channels may be configured
27 in operative relation with the lumen such that a needle backloaded into any of the one or
28 more additional needle guide channels will be advanced out of the additional needle
29 guide channel by pulling on a length of suture that is connected to the needle and
30 threaded though the lumen.

1 The plurality of needle guide channels may come in a variety of shapes. In one
2 embodiment, one or more of the one or more additional needle guide channels is arcuate
3 shaped. Additionally, each of the one or more additional needle guide channels and the
4 first needle guide channel may be arcuate shaped. The plurality of needle guide channels
5 may also be positioned in a variety of ways. In one embodiment, the needle guide
6 channels are circumferentially positioned around the body. In another embodiment, the
7 needle guide channels are circumferentially positioned around the body and are
8 equidistant from each other.

9 In another embodiment, the invention is directed to a medical device comprising a
10 body, a lumen, and a first needle guide channel. The lumen extends from a first lumen
11 opening formed in the body to a second lumen opening formed in the body and is adapted
12 to receive a length of suture. A first arcuate shaped needle guide channel extends from a
13 first needle guide channel opening formed in the body to a second needle guide channel
14 opening formed in the body. The device may also comprise a handle coupled to the
15 body. The handle may be coupled to the body by a connector piece. The device may
16 also comprise one or more additional needle guide channels. Each of the one or more
17 additional needle guide channels may extend from its own first needle guide channel
18 opening formed in the body to its own second needle guide channel opening formed in
19 the body. Each of the one or more additional needle guide channels may have an arcuate
20 shape. The first needle guide channel and each of the one or more additional needle
21 guide channels may be circumferentially positioned around the body and may be
22 equidistant from each other.

23 In yet another embodiment, the device may be comprised of a body, a lumen, a
24 first needle guide channel, a first needle, and a length of suture attachable to the first
25 needle. A length of suture that is "attachable" to a needle means that the suture is not
26 necessarily attached to the needle, but can be attached to the needle. The body may be a
27 variety of shapes, and may be tapered. The lumen may extend from a first lumen opening
28 formed in the body to a second lumen opening formed in the body and is adapted to
29 receive a length of suture. The first needle guide channel may extend from a first needle
30 guide channel opening formed in the body to a second needle guide channel opening
31 formed in the body. The first needle is adapted to be at least partially contained in the

1 first needle guide channel. The length of suture may be coupled to the first needle. The
2 lumen and first needle guide channel are configured in operative relation with each other
3 such that when the needle is backloaded into the first needle guide channel, the needle
4 will be advanced out of the first needle guide channel by pulling on the length of suture
5 that has been connected to the needle and threaded through the lumen. The first needle
6 guide channel may also be arcuate shaped.

7 The medical device may comprise a handle coupled to the body. The handle may
8 be coupled to the body by a connector piece. The connector piece may be bendable such
9 that it can be fixed in a variety of positions. Furthermore, the device may comprise one
10 or more additional needle guide channels, one or more additional needles, and one or
11 more additional lengths of suture. Each of the one or more needle guide channels may
12 extend from its own first needle guide channel opening formed in the body to its own
13 second needle guide channel opening formed in the body. Each of the one or more
14 additional needle guide channels may have its own additional needle adapted to be at
15 least partially contained in the additional needle guide channel. Each additional needle
16 may have its own additional length of suture. Each additional length of suture may be
17 attached to its own additional needle. Each of the one or more additional needle guide
18 channels may be configured in operative relation with the lumen such that when the
19 additional needle corresponding to the additional needle guide channel is backloaded into
20 the additional needle guide channel, the additional needle will be advanced out of the
21 additional needle guide channel by pulling on the additional length of suture that is
22 connected to the additional needle and threaded though the lumen. One or more of the
23 additional needle guide channels may be arcuate shaped. The first needle guide channel
24 and each of the one or more additional needle guide channels may be circumferentially
25 positioned around the body, and in addition may be equidistant from each other.

26 In another embodiment, the device may comprise a body, a lumen, and a first
27 needle guide channel. The body may be a variety of shapes, and in particular may be
28 tapered. The lumen may extend from a first lumen opening formed in the body to a
29 second lumen opening formed in the body and is adapted to receive a length of suture.
30 The first needle guide channel extends from a first needle guide channel opening formed
31 in the body, and the needle guide channel may be arcuate shaped. The lumen and first

1 needle guide channel are configured in operative relation with each other such that when
2 a length of suture is threaded through the lumen and is connected to a needle that is
3 backloaded into the first needle guide channel, and the length of suture is pulled in a first
4 direction, the needle is advanced out of the needle guide channel in a second direction.
5 The first direction has a positive longitudinal component and the second direction has a
6 negative longitudinal component.

7 The device may also comprise a handle coupled to the body. The handle may be
8 coupled to the body by a connector piece that may be bendable such that it can be fixed in
9 a variety of positions.

10 The device may also comprise one or more additional needle guide channels.
11 Each of the one or more needle guide channels may extend from its own first needle
12 guide channel opening formed in the body. The lumen and each of the one or more
13 additional needle guide channels are configured in operative relation with each other such
14 that when a length of suture is threaded through the lumen and is connected to a needle
15 that is backloaded into one of the one or more additional needle guide channels, and the
16 length of suture is pulled in a first direction, the needle is advanced out of the needle
17 guide channel in a second direction. The first direction has a positive longitudinal
18 component and the second direction has a negative longitudinal component. Each of the
19 one or more additional needle guide channels may be arcuate shaped. The first needle
20 guide channel and each of the one or more additional needle guide channels may be
21 circumferentially positioned around the body, and additionally may be equidistant from
22 each other.

23 In a further embodiment, the device is comprised of a first member and a second
24 member. The first member has a first handle and a first jaw. The second member has a
25 second handle and a second jaw. The second member is pivotally connected to the first
26 member. The first jaw comprises of a lumen and a first needle guide channel. A first
27 lumen may extend from a first lumen opening formed in the first jaw to a second lumen
28 opening formed in the first jaw. The lumen should be adapted to receive a length of
29 suture. The first needle guide channel extends from a first needle guide channel opening
30 formed in the first jaw, and the needle guide channel may be arcuate shaped. The lumen
31 and first needle guide channel are configured in operative relation with each other such

1 that a needle that is backloaded into the first needle guide channel will be advanced out of
2 the first needle guide channel by pulling on a length of suture that is connected to the
3 needle and threaded through the lumen.

4 The device may further comprise one or more additional needle guide channels,
5 which may also be arcuate shaped. Each needle guide channel may extend from its own
6 first needle guide channel opening formed in the first jaw. Each of the one or more
7 additional needle guide channels may be configured in operative relation with the lumen
8 such that a needle that is backloaded into any of the one or more additional needle guide
9 channels will be advanced out of the additional needle guide channels by pulling on a
10 length of suture that is connected to the needle and threaded through the lumen. Two
11 needle guide channels in the first jaw may cross each other.

12 In a further embodiment, the second jaw may comprise a lumen and a first needle
13 guide channel. The second jaw may be configured in the same manner previously
14 discussed with respect to the first jaw.

15 In yet another embodiment, the invention is a method of needle placement. The
16 method comprises attaching a first length of suture to a first needle. The first needle is
17 then positioned in the desired location. The first length of suture is then advanced in a
18 first direction, thereby causing the needle to move in a second direction. The first
19 direction has a positive longitudinal component and the second direction has a negative
20 longitudinal component.

21 The method may further comprise attaching one or more additional length of
22 sutures to one or more additional needles. The needles may then be positioned at a
23 desired location. The one or more additional sutures may be advanced in a first
24 additional direction, thereby causing the one or more additional needles attached to the
25 advancing one or more additional lengths of sutures to move in a second additional
26 direction. The first additional direction will have a positive longitudinal component and
27 the second additional direction will have a negative longitudinal component.

28 In further embodiments, the method comprises using a device according to any of
29 the embodiments of the present invention to position the one or more needles.

30 Other embodiments of the present medical devices and methods will be apparent
31 from the detailed description below.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings form part of the present specification and are included to further demonstrate certain aspects of the present invention. The invention may be better understood by reference to one or more of these drawings in combination with the description of illustrative embodiments presented herein. The devices shown in the drawings are not necessarily drawn to scale.

FIG. 1 shows one embodiment of the present invention, wherein the body of the device is depicted in cross section and comprises one arcuate shaped needle guide channel that extends from a first needle guide channel opening to a second needle guide channel opening.

FIG. 2A and **2B** show various configurations of the needle guide channel in cross section. **FIG. 2A** shows a generally straight needle guide channel extending from a single opening. **FIG. 2B** shows an arcuate needle guide channel that also extends from a single opening.

FIG. 3A shows an embodiment of the present invention in cross section that comprises multiple needle guide channels.

FIG. 3B shows a perspective view of one embodiment of the present invention having 6 needle guide channels (3 of which are not visible due to the orientation of the device).

FIG. 4A, 4B, and 4C are cross-sectional views depicting various configurations of the lumen. **FIG. 4A** shows a lumen that extends from a first opening formed in the side of the body to a second opening formed at one end of the body. **FIG. 4B** shows a lumen that extends from a first opening formed in the needle guide channel to a second opening formed in one end of the body. **FIG. 4C** shows a device having multiple lumens.

FIG. 5 shows one embodiment of the present invention in cross section, wherein a needle has been backloaded into the needle guide channel. A suture that is coupled to the needle has been threaded through the lumen.

FIG. 6 shows one embodiment of the present invention in cross section, wherein a needle has been partially advanced out of the needle guide channel by pulling one end of the suture outward from one of the lumen openings.

1 **FIG. 7A** shows one embodiment of the present invention in which a needle guide
2 channel and a lumen have been formed in a first jaw of a clasping device.

3 **FIG. 7B** is a view of a portion of a jaw of a clasping device according to one
4 embodiment of the present invention, in which a needle guide channel and lumen have
5 been formed in the same manner shown in **FIG. 4B**.

6 **FIG. 7C** shows a portion of the jaws of the clasping device in **FIG. 7A** from a
7 perspective that reveals an opening in one of the two jaws through which a needle may be
8 advanced.

9 **FIG. 7D** shows a portion of the jaws of a clasping device according to another
10 embodiment of the present invention, where one of the jaws includes two, crossed needle
11 guide channels.

12 **FIG. 8** shows an embodiment of the present invention in which two needle guide
13 channels are staggered.

14 **DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS**

15 As a preliminary matter, it should be noted that in this document (including the
16 claims), the terms “comprise” (and any form thereof, such as “comprises” and
17 “comprising”), “have” (and any form thereof, such as “has” and “having”), and “include”
18 (and any form thereof, such as “includes” and “including”) are open-ended transitional
19 terms. Thus, a thing (such as a medical device or a needle placement method) that
20 “comprises,” “has,” or “includes” one or more elements possesses those one or more
21 elements, but is not limited to only possessing those one or more elements. For example,
22 a medical device “comprising” a body, a lumen extending between openings formed in
23 the body, and a first needle guide channel extending between needle guide channel
24 openings formed in the body is a medical device that has, but is not limited to only
25 having, these items. In other words, the medical device possesses a body, a lumen
26 extending between openings formed in the body, and a first needle guide channel
27 extending between needle guide channel openings formed in the body, but is not
28 excluded from possessing additional elements or features that are not listed.

29 The device of the present invention facilitates the placement of one or more
30 needles and their attached sutures in areas of the body of a surgical patient that may
31 otherwise be difficult to suture. The device allows for the quick and accurate placement

25084028.1

1 of one or more needles in difficult stitches with one motion. The device may be
2 positioned at various places within the body of a surgical patient. Once the device is
3 positioned, a needle that has been loaded into the device may be positioned in the tissue
4 surrounding the device by pulling on a suture coupled to the needle. When the suture is
5 pulled, the needle is advanced out of the device and will pierce and be positioned in the
6 tissue that is located adjacent to the device.

7 **FIG. 1** shows one embodiment of a device of the present invention. The device
8 has a body **10** that may be made of any material suitable for use in surgical applications,
9 such as plastic. In one embodiment, body **10** is tapered at a first end **11**. This helps to
10 facilitate the placement of the device in the body of a surgical patient. Depending on the
11 particular surgical application for which the device is to be used, body **10** may be shaped
12 in a variety of ways in order to maximize the ability to position the device during the
13 particular surgical procedure. For instance, body **10** may be generally straight and
14 elongated, as shown in **FIG. 1**. Alternatively, if the device is to be used in a surgical
15 application where it would be advantageous for the body to have a curved shape such that
16 the body can more easily be positioned at a desired location in the patient, then body **10**
17 may have a curved shape.

18 Additionally, if the device will be used to place sutures within the walls of a tissue
19 cavity possessing a particular diameter, body **10** of the device may be designed to have a
20 diameter commensurate with the size of the cavity to be sutured. This will facilitate the
21 ability to position one or more needles within the cavity. Those skilled in the art will
22 realize that the body may be shaped in a variety of ways to maximize the performance of
23 the device in a given surgical application.

24 Body **10** also comprises one or more needle guide channels **12** that are formed in
25 the body. The needle guide channel is configured to at least partially receive a needle
26 that may be placed in the needle guide channel. As shown in **FIG. 1**, needle guide
27 channel **12** extends from a first needle guide channel opening **13** formed in body **10** to a
28 second needle guide channel opening **14** formed in the body **10**. As shown in **FIG. 1**,
29 needle guide channel **12** may be arcuate shaped, and may therefore be configured to
30 receive an arcuate shaped needle. Those skilled in the art will realize that the needle
31 guide channel may be configured in a variety of ways. For instance, needle guide

1 channel 20 may extend from only a first needle guide channel opening 21 and be
2 generally straight as shown in FIG. 2A. In another embodiment, needle guide channel 22
3 may be arcuate shaped, but extend from only a first needle guide channel opening 23, as
4 shown in FIG. 2B. The needle guide channels may also be positioned at various
5 positions along the body of the device. For example, the needle guide channels may be
6 positioned nearer to first end 11 of body 10, nearer to second end 18 of body 10, or in
7 approximately the middle of body 10. The positioning of the needle guide channels in
8 the body of the device may be dictated by the area of the patient's body that is to be
9 sutured. Those skilled in the art will realize that the needle guide channels may be
10 positioned to maximize performance for suturing a particular area of a patient's body.

11 Furthermore, the device may contain a plurality of needle guide channels. For
12 example, the device of the present invention may have one, two, three, four, five, six, or
13 more needle guide channels. The number of needle guide channels should fit the
14 application. One embodiment of a device comprising multiple needle guide channels 30
15 is shown in FIG. 3A. As previously stated, the needle guide channels may have a variety
16 of configurations, and each of the plurality of needle guide channels need not have the
17 same configuration. In one embodiment, the needle guide channels are circumferentially
18 positioned about the body of the device. In another embodiment, the needle guide
19 channels are circumferentially positioned about the body of the device, and are
20 approximately equidistantly spaced in relation to each other. A perspective view of such
21 a device that has 6 needle guide channels 30 shown by their own first and second needle
22 guide channel openings 32 and 34 appears in FIG. 3B (three of the sets of openings are
23 not visible due to the orientation of the device). Such a configuration allows multiple
24 needles to be uniformly positioned in a surgical patient when the needles are advanced
25 out of the needle guide channels.

26 As shown in FIG. 1, the device of the present invention also comprises a lumen
27 15 that extends through body 10 from a first lumen opening 16 to a second lumen
28 opening 17. The lumen should be of sufficient diameter that one or more sutures can be
29 threaded through the lumen 15. The lumen may be configured in a variety of ways. For
30 example, in the embodiment shown in FIG. 1, the lumen extends from first lumen
31 opening 16 formed in first end 11 of body 10 to second lumen opening 17 formed in

1 second end 18 of the body. Alternatively, as shown in **FIG. 4A**, lumen 40 may extend
2 from first lumen opening 41 formed in the side of body 10 to second lumen opening 42
3 formed in second end 18 of body 10. In another embodiment shown in **FIG. 4B**, first
4 lumen opening 41 may be formed in wall 80 of needle guide channel 43. In any
5 embodiment, one of the lumen openings can be located at a position in the body of the
6 device such that a person using the device will be easily able to grasp a suture that is
7 extending from that lumen opening.

8 In another embodiment, more than one lumen may be formed in the body of the
9 device. For example, each needle guide channel may have its own designated lumen.
10 **FIG 4C** shows one embodiment of the device in which first needle guide channel 44 and
11 second needle guide channel 45 are formed in body 10. First lumen 47 and second lumen
12 48 are also formed in the body. First lumen 47 is positioned such that a suture coupled to
13 a needle that is positioned in first needle guide channel 44 may be threaded through first
14 lumen 47. Second lumen 48 is positioned such that a suture coupled to a needle that is
15 positioned in second needle guide channel 45 may be threaded through second lumen 48.
16 Those skilled in the art will recognize that the lumen or lumens of the present devices
17 may be configured in a variety of other ways in addition to those described here.

18 As shown in **FIG. 1**, the device may also include a handle 19 that is connected to
19 the body 10 by a connector piece, such as shaft 20. The handle may be made of any
20 suitable material, such as plastic. The handle may be configured such that it can easily be
21 grasped by one hand of a person using the device, such as by placing ergonomic
22 indentions in the handle. In one embodiment, shaft 20 that connects handle 19 to body 10
23 may be bent in one or more places, as is shown in **FIG. 1**, in order to allow for the more
24 accurate placement of the device during suturing. Those skilled in the art will realize that
25 the connector piece may also be configured in a variety of other positions such that the
26 configuration of the connector piece allows the body of the device to be maneuvered in a
27 way that is most advantageous for the particular area being sutured. The connector piece
28 may be made of a flexible material that allows the operator of the device to configure the
29 connector piece in a variety of positions. The connector piece may be comprised of a
30 number of suitable materials. One preferred material is stainless steel gauge wire.

1 Furthermore, shaft **20** and handle **19** may be made from the same material so as to form a
2 unitary structure, or different materials, as shown in the present figures.

3 An example of one embodiment of the present devices in which a needle **50** and
4 suture **51** have been loaded is illustrated in **FIG. 5**. Suture **51** may be made from any
5 material suited to the application, including an absorbable or chromic material used in
6 urethral anastomosis cases. As shown in **FIG. 5**, needle **50** has been backloaded into
7 needle guide channel **52**. The term "backloaded" means that the needle is positioned in
8 the needle guide channel such that it will be advanced, sharp end first, out of the needle
9 guide channel by the suture when an end of the suture is pulled. First end **53** of the suture
10 may be coupled to needle **50**. As illustrated in **FIG. 5**, in one embodiment, suture **51**
11 extends through needle guide channel **52**, through first lumen opening **56**, and through
12 lumen **54** such that second end **55** of suture **51** extends out of second lumen opening **57**.
13 When the device is being used, the needle or needles will be positioned in their respective
14 needle guide channels such that the sharp end or ends of the needle or needles are located
15 within the needle guide channel or channels. This will prevent the needle or needles from
16 becoming accidentally lodged in any tissue as the device is being positioned within the
17 patient's body. Once the device has been positioned such that the needle guide channel
18 opening nearest to the sharp end of the needle contained in the needle guide channel is
19 adjacent to the location where it is desired that the needle be placed, the second end of the
20 suture may be pulled to advance the needle into the desired location.

21 When the second end **55** of the suture is pulled outward from the second lumen
22 opening, needle **50** is advanced out of needle guide channel **52**. Because the needle is
23 backloaded in the needle guide channel, the sharp end of the needle will be the leading
24 end of the needle as the needle advances from the needle guide channel. When the
25 second end of the suture is pulled outward from the second lumen opening, the needle
26 advances out of the needle guide channel such that at least one of the directional
27 components of the needle is opposite to at least one of the directional components of the
28 second end of the suture. Thus, it is the suture itself that advances the needle out of the
29 needle guide channel. Advantageously, this eliminates the need for the surgeon to
30 manually grasp and position the needle in the tissue of the patient.

1 **FIG. 6** shows a needle **60** that has partly been advanced out of needle guide
2 channel **61** by pulling the second end of suture **62** outward from the second lumen
3 opening **63**. One arrow **64** represents the direction in which the second end of the suture
4 is pulled. Two arrows **65a** and **65b** represent the directional components of the needle as
5 it is advanced out of the needle guide channel. As **FIG. 6** shows, the needle has at least
6 one directional component, represented by arrow **65a**, that is opposite in direction to one
7 of the directional components, represented by arrow **64**, of the second end of the suture.

8 **FIG. 7A** shows another embodiment of the present invention that takes the form
9 of a clasp device, sometimes referred to as a hemostat. The clasp device shown in
10 **FIG. 7A** includes a first member **81** (shown in partial cross section) having a first jaw **70**
11 and a first handle **71**, and a second member **82** having a second jaw **72** and a second
12 handle **73**. First and second members **81** and **82** may be pivotally connected to each
13 other in any suitable fashion, including through the use of, for example, a pin or rivet.
14 The respective jaws and handles of a given member may be portions of a single structure,
15 or may be separate pieces of material coupled to each other in any suitable fashion, such
16 as through interlocking parts, glue, welding, nuts and bolts, etc. The embodiment shown
17 in **FIG. 7A** is particularly advantageous because the two jaws may be used to grip the
18 area to be sutured, and then the needle can be placed at the desired location. A needle
19 guide channel **74** is formed in first jaw **70**.

20 As was true of the previous embodiments, the needle guide channel may be
21 configured in a variety of ways. For instance, needle guide channel **74** may extend from
22 a first needle guide channel opening **75** to a second needle guide channel opening **76**, as
23 shown in **FIG. 7A**. Alternatively, the needle guide channel may only have one needle
24 guide channel opening. The needle guide channel may also be shaped in various ways
25 such that the needle guide channel is shaped to receive a needle of a specified shape. For
26 instance, the needle guide channel may be arcuate shaped so as to receive an arcuate
27 shaped needle (as shown in **FIG. 7A**), or may generally straight (as shown in **FIG. 2A**)
28 so as to receive a traditional straight needle. In another embodiment, needle guide
29 channel **74** may be arcuate shaped, but extend only from a first needle guide channel
30 opening, such as needle guide channel **22** shown in **FIG. 2B**. In another embodiment,
31 lumen **77** may extend from first lumen opening **90** formed in wall **92** of needle guide

1 channel 74, as shown in **FIG. 7B**. In addition, the embodiment of the present invention
2 shown in **FIG. 7A** may have multiple needle guide channels to facilitate the placement of
3 multiple sutures, as discussed above with respect to body 10. Specifically, either or both
4 jaws may have one or more needle guide channels, depending upon the application for
5 which the clasp device will be used.

6 As shown in **FIG. 7A**, second member 82 may have opening 94 (shown in dotted
7 lines) disposed within second jaw 72. Opening 94 allows for a needle that is advanced
8 out of needle guide channel 74 to advance without being obstructed by second jaw 72.
9 **FIG. 7C** shows a perspective view of first and second jaws 70 and 72 and, in particular,
10 opening 94. Opening 94 may be configured with any shape suited to allowing a needle
11 advancing out of a relevant needle guide channel in one jaw to advance without
12 obstruction from the other jaw. Multiple openings may be used as necessary when
13 multiple needle guide channels are used.

14 As shown in **FIG. 7A**, in one embodiment, a lumen 77 that extends from a first
15 lumen opening 78 to a second lumen opening 79 may also be formed in first jaw 70. The
16 lumen should be of such a diameter that it may receive at least one suture that is threaded
17 through the lumen. In another embodiment, a needle guide channel and lumen are also
18 formed in the second jaw. As with the embodiments discussed above, in instances of
19 multiple needle guide channels, one or more lumens may be used, such as the
20 configuration discussed above in which each needle guide channel has its own lumen.

21 **FIG. 7D** shows the clasp device of **FIG. 7A** in which multiple needle guide
22 channels are used. Specifically, in one embodiment, as shown in **FIG. 7D**, first jaw 70
23 may have two needle guide channels 74 and 95 (shown in dotted lines and which can be
24 referred to as first and second needle guide channels). Needle guide channel 95, which
25 extends from its respective first needle guide channel opening 96 to its respective second
26 needle guide 100. A lumen – which is adapted to receive a length of suture and
27 configured in operative relation with needle guide channel 95 such that when a length of
28 suture is threaded through the lumen and is connected to a needle that is backloaded into
29 needle guide channel 95, and the length of suture is pulled in a first direction, the needle
30 is advanced out of needle guide channel 95 in a second direction – extends between a first

1 lumen opening **100** to a second lumen opening (not shown). As shown in **FIG. 7D**,
2 needle guide channels **74** and **95** cross each other.

3 The methods and devices of the present invention have a variety of uses. For
4 example, the present devices may be used to place one or more needles for anastomosis
5 of tubular-to-tubular structures, of tubular structure-to-skin as in colostomy or ileal loop
6 diversion, or for suturing of tissue in a side-to-side fashion. As previously indicated,
7 those skilled in the art will recognize that the design of the present devices may be easily
8 adjusted to suit the location and position of the tissues to be sutured. Once a device has
9 been used to place the needles in the desired location in the body of the surgical patient,
10 the doctor may then grasp the needles, withdraw the device from the patient's body, and
11 proceed with the suturing procedure.

12 One surgical specialty in which the present devices would be particularly useful is
13 the radical prostatectomy. A radical prostatectomy requires the joining of the urethra to
14 the bladder. This procedure is known as an anastomosis. The position of the urethra and
15 the pubic bone are such that there is little flexibility in exposure for needle placement.
16 The present invention is particularly well suited for suturing following a radical
17 prostatectomy. For instance, one embodiment of the present invention may be used
18 wherein multiple needles may be backloaded into needle guide channels that are located
19 circumferentially around the body of the device. Each needle should have a suture
20 coupled to it, and the sutures should be threaded through the lumen. The device may then
21 be positioned within the urethra such that when the needles are advanced out of the
22 needle guide channels, the needles will pierce the urethra, and will be positioned around
23 the circumference of the urethra. After the needles have been advanced out of the needle
24 guide channels, the doctor may then grasp the needles, withdraw the device from the
25 body, and finish the suturing procedure.

26 All of the medical devices and methods disclosed and claimed can be made and
27 executed without undue experimentation in light of the present disclosure. While the
28 medical devices and methods of this invention have been described in terms of certain
29 embodiments, it will be apparent to those of skill in the art that variations may be applied
30 to the medical devices and/or methods described herein without departing from the scope
31 of the invention. For example, **FIG. 8** shows an embodiment of the present medical

1 devices in which two needle guide channels are staggered, unlike those shown in **FIG.**
2 **3B**. Specifically, **FIG. 8**, when compared to **FIG. 1**, shows the addition of needle guide
3 channel **100**, which extends from its own first needle guide channel opening **101** in body
4 **10** to its own second needle guide channel opening **102** in body **10**. As another example,
5 multiple needle guide channels could be arranged circumferentially around the body of
6 the present medical devices (or a jaw when the medical device is a clasping device) in
7 two or more staggered groups, with one group being positioned at one distance from an
8 end of the body (such as the distance between first needle guide channel opening **13** and
9 first end **11** of body **10** in **FIG. 8**, for example), another group being positioned a second
10 distance from the same end of the body (such as the distance between first needle guide
11 channel opening **101** and first end **11** of body **10** in **FIG. 8**, for example), etc.
12 Additionally, when multiple needle guide channels are positioned in a single medical
13 device, the needle guide channels may have the same or different lengths. Further, the
14 needle guide channels may cross each other, as shown in **FIG. 7D**. This is true even for
15 needle guide channels disposed in the type of body depicted in **FIG. 3B**, for example.